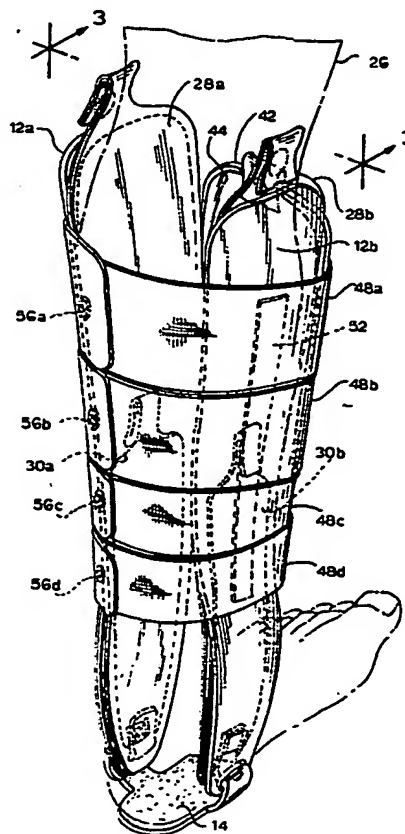




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(54) Title: PNEUMATIC BRACES		
(57) Abstract		
<p>A pneumatic brace comprising at least one outer shell member (12a, 12b) and at least first and second pressurizable chambers (28a, 30a, 28b, 30b) juxtaposed therewith in an overlapping manner for providing a supporting cushion between said outer shell member and a body part or limb. One of said chambers is coextensive with substantially the entire inner surface of said one outer shell member for engagement with a corresponding portion of said body part or limb, while the other of said chambers is coextensive with a portion of said first chamber. In one preferred embodiment, the first and second chambers comprise separate inflatable airbags of different size disposed on said outer shell member with the smaller airbag positioned coextensively with the bottom portion of the larger airbag and between said larger airbag and said inner surface of said outer shell member. In alternatively preferred embodiments, the first and second chambers are integrally formed from a single inflatable liner (60, 60') having two compartments divided by a common wall, at least one of said compartments being selectively inflatable through integral valve means (74, 108) formed at least in part by said common wall.</p>		



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PNEUMATIC BRACESRelated Application

The present application is a continuation-in-part of my prior co-pending application, Serial No. 06/809,198, filed December 16, 1985.

Field of Invention

The present invention relates generally to new and useful improvements in orthopedic braces, and more particularly, to improvements in pneumatic braces featuring one or more rigid outer shell members having associated therewith an inflatable liner or airbag for engaging a body part or limb.

Background Art

Pneumatic braces of the foregoing type are fully disclosed in my prior U.S. patent No. 4,280,489 and prior pending U.S. patent application, Serial No. 06/694,700, filed January 25, 1985. Commercial embodiments of the pneumatic brace incorporating the inventions disclosed and claimed in my prior patent and application and adapted to be fitted about the lower leg typically comprise an outer shell member in the form of a U-shaped stirrup, inflatable liners or airbags disposed within the stirrup member in coextensive relation to the upstanding sidewalls thereof, and strap fastening means for maintaining the stirrup member sidewalls in engagement with confronting portions of the lower leg whereby each airbag serves as a firm supporting cushion of pressurized air between the irregular contours of the lower leg and the stirrup member sidewalls.

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Because this brace construction is capable of stabilizing the ankle against eversion and inversion without restricting dorsiflexion and plantoflexion while being worn inside a conventional shoe, ambulatory functionality and permitted exercises are feasible thereby encouraging more rapid recovery from various injuries to the lower extremity, e.g. ankle sprains, than otherwise would be possible. As a result of these and other important advantages, the commercial embodiments referred to above which are marketed by AIRCAST INCORPORATED, Summit, New Jersey, have become widely accepted and recognized throughout the medical and orthopedic community. See for example, Ramey, H. and Jakob, R.P., "Functional Treatment of Fresh Fibular Ligament Lesions Using the AIRCAST* Ankle Brace", Swiss Journal of Sports Medicine, 2-31:53-57, June, 1983; Stover, C.N. and York, J.M. "AIRCAST/AIR-STIRRUP* System For Graduated Management of Lower Extremity Injuries", Scientific Exhibit Paper, American Association of Orthopedic Surgeons, San Francisco, 1979; Stover, C.N., "AIR-STIRRUP Management of Ankle Injuries in the Athlete", American Journal of Sports Medicine, 8-5:360-365, 1980; and Hamilton, W.G., "Sprained Ankles in Ballet Dancers", Foot and Ankle, 3-2:99-102, 1982.

As disclosed in my prior '489 patent, column 6, lines 16-31, dorsiflexion of the ankle by a wearer of the patented pneumatic brace causes momentary increase in the internal pressure of each airbag. It is believed by at least some of the authors cited above that this alternating pressure exerts a "milking

* AIRCAST is a trademark and AIR-STIRRUP is a registered trademark of AIRCAST INCORPORATED, Summit, New Jersey.

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effect" on edematous tissues during function which in turn, contributes to a more rapid recovery and/or reduction in swelling.

It has also been demonstrated by the JOBST COMPANY, Peoria, Illinois, that treatment of lymphedema may be facilitated by the use of a compression stocking worn about the lower leg. The JOBST compression stocking enhances graduated application of pressure to the lower leg, i.e. relatively greater pressure is applied to the ankle region as opposed to that applied along portions of the lower extremity displaced above the ankle.

However, since the JOBST graduated compression stocking is elastic, it fails to provide sufficient pulsating pressure to achieve the desired pumping or milking effect during ambulatory function.

Certain disadvantages also persist with respect to the AIR-STIRRUP pneumatic brace described in my '489 patent. For example, if the bottom-most fastening straps proximal to the ankle are tightened first, the single airbag in each upstanding sidewall may be over compressed in the ankle region possibly resulting in uncomfortable contact between the bony portions of the ankle (i.e. the malleoli) and the outer hard shell of the brace. Further, in the leg brace version of the AIR-STIRRUP brace which has a greater longitudinal extent along the lower leg than does the ankle brace version, the magnitude of pressure pulsation is less because the larger volume of the airbag used in the leg brace vis-a-vis the ankle brace tends to attenuate compression due to dorsiflexion.

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Disclosure of the Invention

Against the foregoing background, it is a primary object of the present invention is to provide an improved pneumatic brace having means for overcoming the aforementioned disadvantages.

5 It is another object of the present invention to provide an improved pneumatic brace having means for applying a graduated application of pressure to the lower leg, i.e. greater supporting pressure in the ankle region relative to that applied against portions of the leg displaced above the ankle.

10 Toward the accomplishment of these and additional objects and advantages, the pneumatic brace of the present invention briefly described comprises at least one outer shell member and at least first and second pressurizable chambers juxtaposed therewith in an overlapping manner for providing a
15 supporting cushion between said outer shell member and a body part or limb. One of said chambers is coextensive with substantially the entire inner surface of said one outer shell member for engagement with a corresponding portion of said body part or limb, while the other of said chambers is coextensive with a portion of
20 said first chamber. In one preferred embodiment, the first and second chambers comprise separate inflatable airbags of different size disposed on said outer shell member with the smaller airbag positioned coextensively with the bottom portion of the larger airbag and between said larger airbag and said inner surface of
25 said outer shell member. In alternatively preferred embodiments, the first and second chambers are integrally formed from a single inflatable liner having two compartments divided by a common wall, at least one of said compartments being selectively inflatable

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through integral valve means formed at least in part by said common wall.

Brief Description of Drawings

The preceeding and still further features and advantages of the present invention as well as a more complete understanding thereof will be made apparent from a study of the following detailed description of the invention in connection with the accompanying drawings wherein:

FIGURE 1 is a diagramatic, exploded, perspective view of a first preferred embodiment of the present invention;

FIGURE 2 is a schematic, perspective view of the embodiment of FIGURE 1 assembled and fitted about an imaginary lower extremity of a human;

FIGURE 3 is a sectional view in elevation of the embodiment of FIGURE 1 assembled together and fitted about the aforesaid imaginary lower extremity taken along line 3-3 of FIGURE 2;

FIGURE 4 is a sectional view taken along line 4-4 of FIGURE 3;

FIGURE 5 is a sectional view taken along line 5-5 of FIGURE 3;

FIGURE 6 is a diagramatic, exploded, perspective view of an alternatively preferred embodiment of the present invention comprising an integral, dual-chamber airbag;

FIGURE 7 is a view in elevation of the alternatively preferred embodiment of FIGURE 6 as assembled;

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FIGURE 8 is a sectional view taken along line 8-8 of
FIGURE 7;

FIGURE 9 is a sectional view taken along line 9-9 of
FIGURE 7;

5 FIGURE 10 is a sectional view taken along line 10-10 of
FIGURE 7;

FIGURE 11 is a diagrammatic exploded, perspective view of
yet another alternatively preferred embodiment of the present
invention comprising an integral, dual-chamber airbag;

10 FIGURE 12 is a view in elevation of the alternatively
preferred embodiment of FIGURE 11 as assembled;

FIGURE 13 is a sectional view taken along line 13-13 in
FIGURE 12;

15 FIGURE 14 is a sectional view taken along line 14-14 in
FIGURE 12;

FIGURE 15 is a sectional view taken along line 15-15 in
FIGURE 12; AND

20 FIGURE 16 IS A SECTIONAL VIEW TAKEN ALONG LINE 13-13 OF
figure 12, but showing a slightly modified version of the
alternatively preferred embodiment of FIGURE 11.

Best Mode of Carrying Out the Invention

Turning initially to FIGURES 1 and 2, a first preferred
embodiment of the present invention comprises a pneumatic brace
generally represented by reference numeral 10 similar in many
25 respects to the pneumatic brace described in my prior U.S. patent
No. 4,280,489 and co-pending U.S. patent application, Serial No.
06/694,700, filed January 25, 1985, the disclosure of each of

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which is hereby incorporated into the present specification by this reference and made part hereof. Thus, brace 10 in its initial preferred form is adapted to be fitted about the lower extremity of a human and comprises a pair of outer shell members 12a, 12b preferably of a stiff, durable, molded plastic material generally shaped to conform to the lateral and medial sides of the lower extremity, respectively, and a base member 14 having a pair of oppositely extending, hinge portions 16a, 16b. Preferably, the base member 14 and hinge portions 16a, 16b are formed from a common piece of flexible woven mylon material cut to size and shaped substantially as shown, and have bonded thereto a layer of fastener material such as that commonly sold under the VELCRO trademark.

As best seen in FIGURES 3 and 5, the distal ends 18a, 18b of hinge portions 16a, 16b are adapted to be inserted through transverse slots 20a, 20b proximal to the lower edges 22a, 22b of shell members 12a, 12b and thereupon be fastened to a pair of mating VELCRO fastener patch elements 24a, 24b in slightly spaced relation above slots 20a, 20b, preferably by means of a suitable adhesive. It will be apparent that when the shell members and the base portion are so assembled, there is formed a U-shaped stirrup member adapted to be fitted about the lower extremity with the heel of the foot resting upon the base member and the opposed shell members forming a pair of upwardly extending sidewall portions adapted to be flexed or displaced via hinge portions 16a, 16b into confronting engagement with corresponding opposed side portions of the lower extremity substantially as depicted in

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FIGURES 2 and 5 with the lower extremity (i.e. the right leg, ankle, and foot of a human) being indicated schematically by broken line 26.

In my patented pneumatic brace, there is provided a
5 single flexible, inflatable airbag or liner on the inwardly facing surface of each sidewall member. In accordance with the present invention, the initial preferred embodiment disclosed herein departs significantly from this prior arrangement by featuring a pair of separate, differently size, flexible, inflatable airbags
10 28a, 28b and 30a, 30b disposed in a juxtaposed, overlapping manner on the inwardly facing, confronting surfaces of sidewall members 12a, 12b substantially as shown in FIGURES 3-5.

Thus, sidewall member 12a has associated therewith a first inflatable airbag 28a which extends substantially
15 coextensively with respect to the inner surface 15a of sidewall member 12a, and a second inflatable airbag 30a which extends substantially coextensively with respect to approximately the bottom half of both the inner surface 15a and the corresponding confronting surface of airbag 28a, i.e. airbag 30a is about one
20 half as large as airbag 28a, is disposed between sidewall member 12a and airbag 28a, and is substantially coextensively aligned with approximately the bottom half portion of airbag 28a.

Likewise, sidewall member 12b has associated therewith a first inflatable airbag 28b extending substantially coextensively
25 with respect to the inner surface 15b of sidewall member 12b, and a second inflatable airbag 30b extending substantially coextensively relative to approximately the bottom half of both the inner surface 15b and the corresponding confronting surface of

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airbag 28b, i.e. airbag 30b is approximately half the size of airbag 28b, is positioned between sidewall member 12b and airbag 28b, and is substantially coextensively aligned with approximately the bottom half portion of airbag 28b.

5 The inflatable, flexible liners or airbags 28a, 28b, 30a, 30b adapted for use with the initial embodiment of this invention preferably are the same type fully described in my co-pending patent application, Serial No. 06/694,700, filed January 25, 1985, (incorporated herein). Hence, each airbag comprises a
10 pair of similarly sized, opposed, thin sheets of pliable material (e.g. vinyl plastic) bonded together along their confronting peripheries using known joining techniques such as heat or electronic bonding, for example. As more fully disclosed in my co-pending application (and my prior patent No. 4,276,920, entitled "Self
15 Sealing Valve", incorporated therein), each such airbag 28a, 28b, 30a, 30b further includes an integral valve 32a, 32b, 34a, 34b extending upwardly therefrom and having a normally sealed throat through which a flexible plastic tube (not shown) may be inserted to facilitate selective inflation or pressurization of each airbag
20 via mouth entubation. Also, each valve may carry exteriorly a pair of spaced, cooperating VELCRO fastener elements to enable the valve to be folded down upon itself and fastened in place thereby presenting a neater appearance and helping to avoid leakage of air through the throat of each valve. It will be appreciated that the
25 invention is not limited to this particular valve construction and other conventional one-way valves for selectively admitting and/or exhausting air to and from the interior of each inflatable airbag may be utilized instead.

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In addition, and as also more fully described in my co-
pending application cited above, each airbag preferably is pre-
inflated by having inserted therein during fabrication a filler
member or pad 36a, 36b, 38a, 38b of compressible, resilient,
5 porous material, preferably open cell urethane foam, shaped and
sized to substantially completely fill the interior volume of each
airbag, respectively, although here again it will be understood
that such filler members are not necessary for practicing and/or
achieving the advantages of the present invention.

10 Thus, whether or not the airbags are pre-inflated
employing filler members 36a, 36b, 38a, 38b, they preferably are
affixed to the opposed, inwardly facing surfaces 15a, 15b of
sidewall members 12a, 12b through suitable application of a con-
ventional adhesive liquid compound (or mating VELCRO fastener
15 elements) such that the attached airbags 28a, 28b substantially
entirely overlap attached airbags 30a, 30b; the integral valves
32a, 32b of airbags 30a, 30b extend above the upper edges 40a, 40b
of sidewall members 12a, 12b; and the overlapping lower portions
of the airbags, in turn, overlap the attached distal ends 18a, 18b
20 of the base member's hinge portions 16a, 16b as most clearly
depicted in FIGURES 2-5. The adhesive compound, if employed,
should be of the well known "tacky" variety which when dry permits
airbags 28a, 28b to be peeled away from the inner surfaces 15a,
15b of shell members 12a, 12b as desired to permit access to the
25 integral valves 34a, 34b on the smaller sized airbags 30a, 30b,
and then reattached. In similar fashion, the bottom portions of
airbags 30a, 30b may be peeled back as desired to permit adjust-

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ment between VELCRO fastener elements 24a, 24b and hinge end portions 18a, 18b, and then reattached.

In accordance with another feature of the present invention, an optional shin guard may be provided in the form of outer shell member 42 fabricated of the same material as sidewall wall members 12a, 12b and shaped to generally conform to the curvature of the anterior portion of the lower extremity. The shin guard preferably includes a single inflatable airbag or liner 44 substantially identical to the construction of airbags 28a, 28b, 30a, 30b, i.e. it preferably features an integral valve 46 and pre-inflation filler pad 48; is sized to coextensively overlies substantially the entire inwardly facing surface 50 with integral valve 46 extending above upper edge 52; and is releaseably attached to surface 50 using a suitable adhesive compound applied thereto or a pair of mating VELCRO fastener elements.

As is evident from the above description, the assembled leg brace of FIGURES 1-5 is intended to be fitted about the lower extremity of a human with the sidewall members 12a, 12b flexed or displaced toward and into engagement with corresponding confronting medial and lateral portions of the foot, ankle and lower leg. In addition, the shin guard is intended to be fitted to engage a corresponding confronting portion of the anterior of the lower leg above the ankle. By such arrangement, airbags 28a, 30a, 28b, 30b and 40 will be compressed sufficiently to provide a pressurized air cushion or envelope circumferentially engaging the lower extremity and filling the voids between the inner surfaces

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of the upstanding sidewall members and the shin guard on the one hand, and the irregular contours of the lower extremity on the other hand.

In order to maintain this desired relationship and the appropriate magnitude of pressurization inside the airbags, the upstanding sidewalls and shin guard advantageously are fastened together and maintained in position relative to the lower extremity by a plurality of elongated, circumferentially extending, longitudinally spaced, flexible fastening straps 48a-d (shown partially broken away in FIGURE 1).

Preferably, each strap 48a-d is fabricated of the same well known woven nylon material as base member 14 and therefore includes a layer of VELCRO fastening material on the underside thereof as viewed in FIGURES 1-5. Each strap is securely affixed to or terminates in a respective VELCRO fastener patch element 50a-d which, in turn, is securely attached to the outer surface of shell member 12b, preferably by means of a suitable adhesive, with the patch elements being adapted to securely mate with the VELCRO fastening material on the underside of each strap member. Thus, in the preferred arrangement, one end of each strap member 48a-d has its corresponding patch element 50a-d anchored to shell member 12a thereby permitting the underside of the other or distal free end of each strap member to be securely fastened to such corresponding fastener patch element after the strap members are circumferentially drawn and tensioned snugly about the exterior of both shell members and the shin guard. Additional longitudinally extending VELCRO fastener elements 52, 54 preferably attached

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respectively to the outer surface of shell member 12b and shin guard member 42, as well as disc-shaped VELCRO fasteners 56a-d attached to the outer surface of straps 46a-d as depicted, may be provided to further matingly engage the portions of the underside of strap members 48a-d in circumferential contact therewith when the strap members are tightened and fastened about the shell members and shin guard. Fastener elements 56a-d are so located along the axis of each corresponding strap 46a-d so that when the latter are circumferentially drawn about the leg brace as shown in FIGURE 2, the undersides of the straps will matingly engage fasteners 56a-d near the distal extremity of each strap preventing the free ends of the straps from dangling in a loose fashion and thus, maintaining a neat appearance.

In practice, leg brace 10 is fitted about the lower extremity by positioning the leg between the shell members 12a, 12b with the heel of the foot resting upon base member 14, and putting on, but not yet lacing the shoe to be worn with the leg brace. The next step is to squeeze or flex the outer shell members 12a, 12b toward each other into engagement with the lower extremity. The bottom-most fastener strap 48d then is circumferentially drawn (tensioned) about both shell members until comfortable, but not excessive compression of the overlapping airbags 28a, 28b and 30a, 30b is achieved in the region of the ankle whereupon the strap is fastened in place via mating patch elements 50d and 56d. The shoes should then be laced up.

If the optional shin guard is to be worn, it should be positioned on the anterior portion of the leg with its bottom edge underneath the bottom fastener strap 48d and the shin guard's side

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edges under the adjacent side edges of shell members 12a, 12b, respectively, before the bottom strap is secured. The upper strap 48a should then be circumferentially drawn about the shell members and shin guard until these parts are comfortably engaging the leg, then fastened in place by engagement with the mating VELCRO fastener elements 50a, 52, 54 and 56a.

Finally, and in similar fashion, the two remaining middle fastening straps, 48b, 48c are circumferentially tensioned in place and fastened.

As described above, the bottom strap 48d should be fastened more snugly or under greater tension than the other straps 48a-c. Since the air inside the larger airbags is displaced upwardly, this helps to assure that the smaller airbags 30a, 30b are placed under sufficient compression to have greater internal pressurization than the larger airbags 28a, 28b, thus achieving the desired graduated compression. That is, greater supporting pressure is applied in the region of the ankle coextensive with airbags 30a, 30b (see FIGURE 3) than is applied in the region above and displaced from the ankle coextensive with the upper half of the larger airbags 28a, 28b.

The desired graduated compression arrangement is further facilitated by initially inflating or pre-inflating the larger airbags 28a, 28b to a relatively lesser extent than the smaller airbags 30a, 30b. If the pre-inflation filler members according to the teachings in my prior co-pending application, cited above, are utilized as preferred, this is accomplished by providing filler members 38a, 38b having a greater transverse thickness as

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measured in the plane of FIGURES 2 and 4 than that of filler members 36a, 36b.

Thus, without limiting the present invention, I have found that excellent results are achievable with a leg brace having outer shell members 16 inches in longitudinal extent, 3.5 inches in transverse extent (maximum), a size ratio of about 2:1 between the larger airbags and the smaller airbags, and pre-inflation filler members having normal (uncompressed) transverse thicknesses measured in the plane of FIGURES 4 and 5 of .150 inches (larger airbags) and .225 inches (smaller airbags), respectively.

Actual experimentation with the foregoing leg brace embodiment under ambulatory conditions was undertaken using pressure transducers attached to each airbag and suitable recording means. It was discovered that in response to dorsiflexion of the ankle the internal pressure of the smaller airbag varied in the range between about 30 mm Hg. (static) to about 60 mm Hg. whereas the internal pressure of the larger airbag varied in the range between about 25 mm Hg. (static) to about 40 mm Hg. It will thus be appreciated that the use of the supplemental smaller airbags 30a, 30b as contemplated by the present invention achieves both graduated compression and pulsating pressure during ambulation as desired.

It also will be noted with particular reference to FIGURE 3 that the disclosed arrangement featuring the smaller airbags 30a, 30b in a location proximal to the bony regions of the ankle (i.e. the malleoli) as substantially illustrated helps to avoid uncomfortable contact between these body parts and the hard

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outer shell members by focusing maximum supporting pressure only in the ankle region. If a single airbag were employed as in the prior arrangement, inflation to a pressure high enough to avoid contact in the ankle region would cuase excessive pressure elsewhere.

While it is true that in the preferred embodiment, the smaller airbags 30a, 30b are placed between the larger airbags 28a, 28b and each outer shell member respectively, it will be understood that this arrangement is not essential, but merely desirable as it affords contact between portions of the leg and the smoother, continuous surface of the larger airbags 28a, 28b rather than the upper extremity and valve of the smaller airbags which would present an interrupted surface in engagement with the leg. Therefore, the present invention should not be so limited to the arrangement illustrated, i.e. in theory, the smaller airbags may be placed between the two lower portions of the larger airbags and the portions of the leg coextensive therewith and still deliver the advantages of graduated compression and pulsating pressure described above.

A subject wearing the leg brace 10 of FIGURES 1-5 may find it necessary from time to time to increase pressurization of the airbags and/or provide more comfort after the initial fitting. Such readjustment may easily be effected by releasably disengaging the bottom strap with one hand and flexing the opposed outer shell sidewall members toward one another sufficiently with the other hand. The bottom strap may then be refastened followed by similar readjustment of the remaining straps.

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If yet additional final adjustment for added comfort or support is required, this may be accomplished by unfastening the leg brace and further inflating one or more airbags 28a, 28b, 30a, 30b 42 by inserting a plastic tube into the throat of valves 32a, 32b, 34a, 34b, 46 and using mouth entubation. As mentioned above, access to valves 34a, 34b for supplemental inflation of airbags 30a, 30b is achieved by peeling back overlapping airbags 28a, 28b, effecting the desired increase in internal pressure via mouth entubation, and then reattaching airbags 28a, 28b to their original position.

Also, it will be observed that the width of base member 14 and the spacing between the shell members 12a, 12b may be adjusted to fit lower extremities of varying size by peeling back the overlapping bottom portions airbags 28a, 28b, and 30a, 30b, releasing the attachment between distal portions 18a, 18b of hinge portions 16a, 16b and VELCRO fasteners 24a, 24b, reattaching as desired, and restoring the overlapping airbag bottom portions to their original position.

In its broadest terms, the preferred embodiment of FIGURES 1-5 features an outer shell member having two pressurizable chambers associated therewith, one chamber being coextensively related to the shell member and the other chamber being coextensively related to a portion of the first chamber. As applied to the embodiment of FIGURES 1-5, the first chamber corresponds to the larger airbags 28a, 28b whereas the other chamber corresponds to the smaller airbags 30a, 30b. I have found that the foregoing arrangement comprising a pair of separate inflatable airbags may

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yet still be further improved by employig the alternatively preferred embodiment illustrated in FIGURES 6-10.

More particularly, I have discovered that a unitary airbag or liner member having a pair of pressurizable chambers is less bulky, less expensive to fabricate, and is aesthetically more desirable than a pair of separate inflatable airbags as disclosed, for example, in connection with the initial preferred embodiment of FIGURES 1-5.

Thus, turning now to FIGURES 6-10 there is shown such a unitary member generally represented by reference numeral 60 comprising three relatively thin, sheets or plies 62, 64, and 66 coextensively joined or bonded together along their common peripheral extents to form a pair of pressurizable chambers interiorly thereof as will be explained in more detail below.

Each ply is fabricated from an air-impervious, tough, flexible material such as vinyl plastic, for example, and cut to the shape substantially as shown on a conventional die cutting press.

Plies 62, 64 are mirror images of one another and include integral extensions 62a, 64a projecting upwardly with respect to their topmost edges, respectively. The extensions 62a, 64a, in turn, are folded along creases 66, 68 to define a pair of confronting end flaps 70, 72. Thus, when plies 62, 64 are bonded together congruently in a manner more fully described in my prior '920 patent, the integral extensions 62a, 64a, and end flaps 70, 72 form a self-sealing valve member 74 (FIGURE 7) adapted to seal any air in a first chamber formed interiorly of the joined plies, thus preventing loss of internal pressurization. As further

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taught in the '920 patent, integral valve 74 may selectively be opened as, for example, by a suitably sized plastic tube inserted between the confronting flaps to admit or exhaust air from the first chamber.

5 In accordance with the preent invention, the first chamber in unitary member 60 is formed coextensively with the bottom portions of plies 62, 64 and preferably is pre-inflated by positioning a first filler member or pad 76 of porous, compressible material (e.g. open cell urethane foam) between the plies before
10 the latter are bonded together along their common peripheral extents as taught in my '920 patent. As best seen in FIGURES 6 and 7, the first filler member 76 has a shape and size conforming substantially to the bottom portions of plies 62, 64 and terminates in a relatively straight, horizontally extending upper
15 boundary 78 defining the upper extremity of the first chamber.

 Plies 62, 64 are also bonded together locally along a pair of seams 80, 82 (FIGURES 7) which extend inwardly from their intersection with the opposed edges of the plies immediately above upper boundary 78 of first filler member 76. Seams 80, 82 then
20 extend arcuately upwardly substantially as shown in spaced relation to one another until they arcuately intersect the upper edges of plies 62, 64 on either side of the base porion defining integral valve extension 74. By this arrangement, a longitudinally extending thru-passage 84 is formed between plies 62, 64 connect-
25 ing valve 74 with the upper portion of the first chamber. The cross-section of passage 84 is shown slightly exaggerated for purposes of clarity in FIGURE 10.

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Prior to bonding plies 62, 64 together along their peripheral extents and along seams 80, 82, an insulating member 86 preferably in the form of a thin disc of paper or TEFLON material is affixed by a suitable, known adhesive to the surface of ply 64 facing ply 62 in a position coinciding with the common upper edge of plies 62, 64 immediately below the extreme necked-down throat portion of valve 74 as clearly shown in FIGURES 6-8. The insulating member 86 prevents plies 62, 64 from being welded or bonded together when ply 66 is subsequently joined to plies 62, 64 to form unitary member 60.

The second chamber in unitary member 60 is formed coextensively with substantially the entire extent of plies 64 and 66, and as is the case with the first chamber, preferably is pre-inflated. This is accomplished by positioning a second filler member 88 of the same material as filler member 76, having a shape and size conforming generally to that of both plies 64, 66 between the plies and then bonding ply 66 to ply 64 (and ply 62) along their common peripheral extents using known heat or electronic sealing methods.

It will be observed that the resulting unitary member 60 comprises a pair of pressurizable chambers divided by a common wall (ply 64) with one of the chambers extending coextensively with respect to substantially the entire member, and the other chamber extending only partially coextensively with respect to the member 60 and the first mentioned chamber, said other chamber being disposed in an overlapping, juxtaposed manner with respect to the bottom portion of said first chamber. The unitary member 60

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also includes valve means 74 for selectively inflating only the other chamber with the valve means being comprised in part by said common wall (see FIGURES 8).

5 In practice, the unitary member 60 of FIGURES 6-10 may be substituted for the inflatable airbags 28a, 28b, and 30a, 30b of the embodiment of FIGURES 1-5 by being attached directly to each sidewall member's inner surface 15a, 15b, respectively, using a suitable adhesive compound a pair of mating VELCRO fastener elements. The unitary member is positioned relative to each
10 sidewall member so that valve 74 extends above the upper edge of each sidewall member, and the overlapping juxtaposed chambers defined by filler members 76, 88 (i.e. the bottom portion of member 60) overlies VELCRO fasteners 24a, 24b and base member hinge end portions 18a, 18b. In such arrangement, it is preferable to
15 place the side of member 60 defined as the smaller chamber (i.e. filler member 76 and ply 62) against surfaces 15a, 15b so that the uninterrupted, smooth surface of the side defined by the larger chamber (i.e. filler member 88 and ply 66) faces oppositely and directly contacts the medial and lateral portions of the lower
20 extremity, respectively.

As is true with respect to the supplemental airbags 30a, 30b of the initial embodiment of FIGURES 1-5, filler member 76 and the pressurizable chamber defined thereby in the lower portion of unitary member 60 is intended to focus maximum supporting pressure
25 in the region of the ankle. Thus, for the same reasons given above in connection with the initial embodiment, it is preferred that filler member 76 have a greater transverse thickness as measured in the plane of FIGURES 8 and 9 than that of filler

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member 88. Without limiting the present invention, I have found that excellent results are achieved using an ankle brace having up-standing sidewall members about 10 inches in longitudinal extent, a filler member (small) having a transverse thickness of about .225 inches, and a filler member (large) having a transverse thickness of about .125 inches.

Nonetheless, it will be understood that the thickness of the small filler member i.e. member 76, may be made less where compensation to achieve the desired internal pressurization of the chamber defined by the smaller filler member is effected by increasing the tension in the bottom-most fastener strap 48d of brace 10 through circumferential tightening of the strap via suitable adjustment of the strap and of mating patch elements 50d and 56d. Because of this flexibility of adjustment, it is feasible for the filler members 76, 88 to have the same thickness which latter may range from about .1 inches to about .5 inches, with a thickness in the range from about .125 inches to about .3 inches being mostly preferred.

Also, it may be desirable to adjust the supporting pressure afforded by filler member 76 in its chamber from time to time. This may easily be accomplished using valve 74 to increase or decrease the internal pressure of the chamber. It will be noted in the alternatively preferred embodiment of FIGURES 6-10 that no such valve is provided in connection with the larger chamber defined by filler member 88, as any adjustment of the internal pressure of the larger chamber normally is not required in view of the excellent graduated compression effect achieved by

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the unitary member, and the adjustability afforded by using valve 74 in connection with the smaller chamber.

Finally, if desired, a pair of VELCRO mating fasteners 90, 92 may be affixed to the valve exterior 74 as shown in FIGURES 6 and 7 so that the valve may be folded upon itself and fastened in place.

An important advantage of the preferred embodiment of FIGURES 6-10 is the ease and relatively reduced cost of manufacture of unitary member 60. Thus, during fabrication, plies 62, 64, and 66 are coextensively aligned relative to one another with filler member 76 appropriately positioned between plies 62 and 64, and filler member 88 appropriately positioned between plies 64 and 66. The stacked arrangement is then engaged by a suitable sealing die and bonded together along the entire peripheral extent thereof and along seams 80 and 82. Owing to placement of insulation disc 92 in the throat of valve 74 on inner surface of ply 64 facing ply 62, the top edge weld or bonded seam 92 between plies 66 and 64 will not print through to ply 62. Likewise, due to the insulating effect of filler member 88, seams 80 and 82 will merely bond plies 62 and 64 together accordingly, but will not print through to ply 66. If desired, the foregoing assembly operation may be accomplished in two steps, i.e. plies 62 and 64 being bonded together initially followed by the step of bonding ply 66 to the partially completed member 60.

Without departing from the principals of the present invention, still other variations in construction of the unitary member are possible. Thus, turning now to the further alternatively preferred embodiments of FIGURES 11-16, where reference

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numeral 60' generally represents the unitary member and where like reference numerals represent similar elements, there is shown an arrangement where the valve integrally formed by two of the plies permits selective pressurization (or depressurization) of the second chamber rather than the first chamber. As in the case of unitary member 60 (FIGURES 6-10), unitary member 60' comprises three relatively thin sheets or plies 62', 64' and 66' coextensively joined or bonded together along their common peripheral extents to form a pair of pressurizable chambers interiorly thereof, with each ply being fabricated from an air-impervious, tough, flexible material such as vinyl plastic, for example, and cut to the shape substantially shown on a conventional die cutting press.

Ply 62' however is shaped in such a manner that it may be folded about a medial line or crease 94 to form a pocket or sleeve comprising a pair of opposed mirror-imaged sections 96, 98 for receiving filler member 76 therebetween such that the upper boundry or terminal edge 78 is juxtaposed proximally to crease 94 and the sleeve and filler member may be positioned coextensively and congruently with respect to the bottom portions of plies 64' and 66' to form the first chamber as best viewed in FIGURES 12 and 13.

The second chamber disposed in unitary number 60' is formed coextensively with substantially the entire extent of plies 64' and 66', and also preferably is pre-inflated by positioning the second filler member 88 which has a shape and size conforming generally to that of both plies, and which is of the same material

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as filler member 76 (e.g. open cell urethane foam) between plies 64' and 66' substantially as shown, before plies 64', 66' and folded ply 62' are bonded together along their common peripheral extents as will be explained more fully below.

5 It will be noted that plies 64', 66' are mirror images of one another and include integral extensions 64'a, 66'a projecting upwardly with respect to their topmost edges, respectively. The extensions 64'a, 66'a, in turn, are folded along creases 100, 102 to define a pair of confronting end flaps 104, 106.

10 Thus, when plies 64', 66' are bonded together congruently in the manner described more fully in my prior '920 patent, the integral extensions 64'a and 66'a and end flaps 104 and 106 form a self-sealing valve member 108 (FIGURE 12) adapted to seal any air in the second chamber formed interiorly of the joined plies 64', 66' 15 thereby preventing loss of internal pressurization. As further taught in the '920 patent, integral valve 108 may selectively be opened as, for example, by a suitably shaped plastic tube inserted between confronting flaps 104, 106 to admit or exhaust air from the second chamber.

20 The provision of the integral valve 108 to permit adjustment in internal pressurization of the second chamber greatly simplifies and lowers the cost of manufacturing the unitary member 60' of FIGURES 11-15. Thus, during fabrication, plies 64' and 66' first are coextensively and congruently aligned relative to one 25 another with filler member 88 placed in appropriate registration therebetween. Ply 62' may then be folded about crease 94 and filler member 76 placed in coextensive and congruent position between sections 96, 98. The resulting sandwich comprising ply

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62' (i.e. sections 96, 98) and filler member 76 next is positioned congruently with respect to the bottom portion of the confronting sandwich formed by ply 64', filler member 88, and ply 66' such that the peripheral margins of the opposed sandwiches are in registration and crease 94 extends substantially horizontally along the transverse extent of unitary member 60' as viewed in FIGURE 12. A suitably configured heat or electronic sealing die may then be employed to engage the entire stacked arrangement comprising the aligned confronting sandwiches of plies and filler members thus joining them together along peripheral seam or weld 110 in a single step.

From the above, it will be appreciated that the resulting unitary member 60' comprises a pair of pressurizable chambers divided by a common wall comprising juxtaposed ply 64' and section 96 of ply 62' with one of the chambers extending coextensively with respect to substantially the entire unitary member, and the other chamber extending only partially coextensively with respect to the first mentioned chamber, i.e. in an overlapping, juxtaposed manner with respect to the bottom portion of said first chamber. The unitary member 60' also includes valve means 108 for selectively inflating or adjusting the internal pressurization of only the other chamber with the valve means being comprised in part by said common wall (see FIGURE 13).

In practice, it will be appreciated that the unitary member 60' of FIGURES 11-16 also may be substituted for the inflatable airbags 28a, 28b, and 30a, 30b of the embodiment of FIGURES 1-5 by being attached directly to each sidewall member's

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inner surface 15a, 15b, respectively, using a suitable adhesive compound or if desired, mating VELCRO fasteners, one element of which, identified by reference numeral 112, may be attached to the outwardly facing surface of section 98 of ply 62' and the other element of which may be affixed by adhesive to the inner surface of the corresponding sidewall member. The unitary member 60', in either case, is positioned and attached relative to each sidewall member so that valve 108 extends above the upper edge of each sidewall member, and the overlapping juxtaposed chambers defined by filler members 76, 88 (i.e. the bottom portion of member 60') overlies VELCRO fasteners 24a, 24b and base member hinge portions 18a, 18b. Here again, it is preferable to place the side of member 60' defined as the smaller chamber side (i.e. filler member 76 and section 98 of ply 62') against surfaces 15a, 15b so that the uninterrupted, smooth surface of the side defined by the larger chamber (i.e., filler number 88 and ply 66') faces oppositely and directly contacts the medial and lateral portions of the lower extremity, respectively, when brace 10 is fitted thereabout.

When valve member 108 is located in such a manner to permit selective pressurization or depressurization of the other or larger chamber defined by filler member 88, the bottom portion of the filler member 88 coextensive and congruent with filler member 76 may be dispensed with. This yet further variation of the alternatively preferred embodiment of FIGURES 11-15 is shown in FIGURE 16, i.e. filler member 88 extends between a top edge 114 and a bottom edge 116 and is generally vertically aligned with the lower or smaller filler member 76 as viewed in FIGURE 16. If such a

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modified arrangement is desired, the folded ply 62' may be es-
chewed in favor of a smaller ply 118 substantially coextensive
with the smaller filler member 76 and bonded to the inside surface
of ply 64' along a seam or weld 120 defined by the common per-
5 ipheral extents of plies 118 and 64'. After plies 118 and 64' are
bonded together accordingly, a second bonding/sealing operation is
necessary to bond ply 66' to ply 64' and ply 118 along seam 110
after the upper filler member 88 has been positioned substantially
as shown in FIGURE 16.

10 It will thus be seen that the alternative embodiments of
FIGURES 6-10 and of FIGURES 11-16 are capable of achieving all of
the advantages of the initial embodiment of FIGURES 1-5, yet offer
obvious added improvement in terms of simplicity of construction,
reduced bulk, and a more aesthetic appearance.

15 As used herein, the term "lower extremity" should be
interpreted broadly to include the foot, the ankle, and the lower
leg.

Obviously, many other modifications and alterations of
the present invention will occur to these with ordinary skill.

20 Accordingly, the present invention should be limited only by the
spirit and scope of the appended claims.

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Claims

1. Orthopedic apparatus comprising:

an outer shell member adapted to engage a body part in supporting relation thereto, and

first and second pressurizable chambers disposed on said outer
5 shell member for providing a supporting cushion between said outer
shell member and said body part,

said first chamber being substantially coextensive with at
least a portion of said outer shell member, and

said second chamber being coextensive with a portion of said
10 first chamber.

2. The apparatus of claim 1 further comprising means for main-
taining said outer shell member in engagement with said body part
such that the supporting pressure applied against said body part
by said second chamber is relatively greater in magnitude than the
5 supporting pressure applied against said body part by the portion
of said first chamber displaced from the portion thereof coexten-
sive with said second chamber.

3. The apparatus of claim 2 wherein said outer shell member
comprises a base portion and a pair of sidewall members attached
to opposite sides of said base portion, said first and second
pressurizable chambers being disposed on at least one of said
5 sidewall members in an overlapping manner with said second chamber
being coextensive with the bottom portion of said first chamber
proximal to said base portion.

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4. The apparatus of claim 3 wherein said second pressurizable chamber is disposed on said at least one side wall member between said sidewall member and said first chamber.

5. The apparatus of claim 3 wherein said first and second pressurizable chambers comprise separate inflatable airbags respectively, each having valve means for selectively increasing or decreasing the internal pressurization thereof.

6. The apparatus of claim 5 wherein each said separate airbag is pre-inflated to a predetermined extent by having disposed therein a porous, compressible member filling substantially the entire interior volume thereof.

7. The apparatus of claim 2 wherein said first and second pressurizable chambers are joined together via a common wall to form a unitary member.

8. The apparatus of claim 7 wherein said common wall has valve means disposed at one end thereof and said second pressurizable chamber disposed at another end thereof, said unitary member further comprising passage means on said common wall connecting
5 said valve with said second chamber.

9. The apparatus of claim 8 further comprising a second wall and a third wall joined coextensively to said common wall along the common peripheral extents thereof, said common wall and said third wall defining said first chamber, said common wall and said second
5 wall defining said second chamber, said common wall and said second wall being joined together along a pair of spaced seams to

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define said passage connecting said valve and said second chamber wherein said second chamber is disposed coextensively with the bottom portion of said first chamber below one end of said pair
10 of spaced seams, the other end of said pair of spaced seams terminating proximal to said valve whereby said passage communicates the upper portion of said second chamber therewith.

10. The apparatus of claim 9 further including means disposed on said common wall in the vicinity of said other end of said pair of spaced seams and said valve to prevent closure of said valve when
5 said third wall is joined to said common wall to form said first chamber.

11. The apparatus of claim 7 further comprising valve means formed at least in part by said common wall for admitting or releasing pressurized air from one of said chambers.

12. The apparatus of claim 11 wherein said one chamber comprises said first chamber.

13. The apparatus of claim 11 wherein said one chamber comprises said second chamber.

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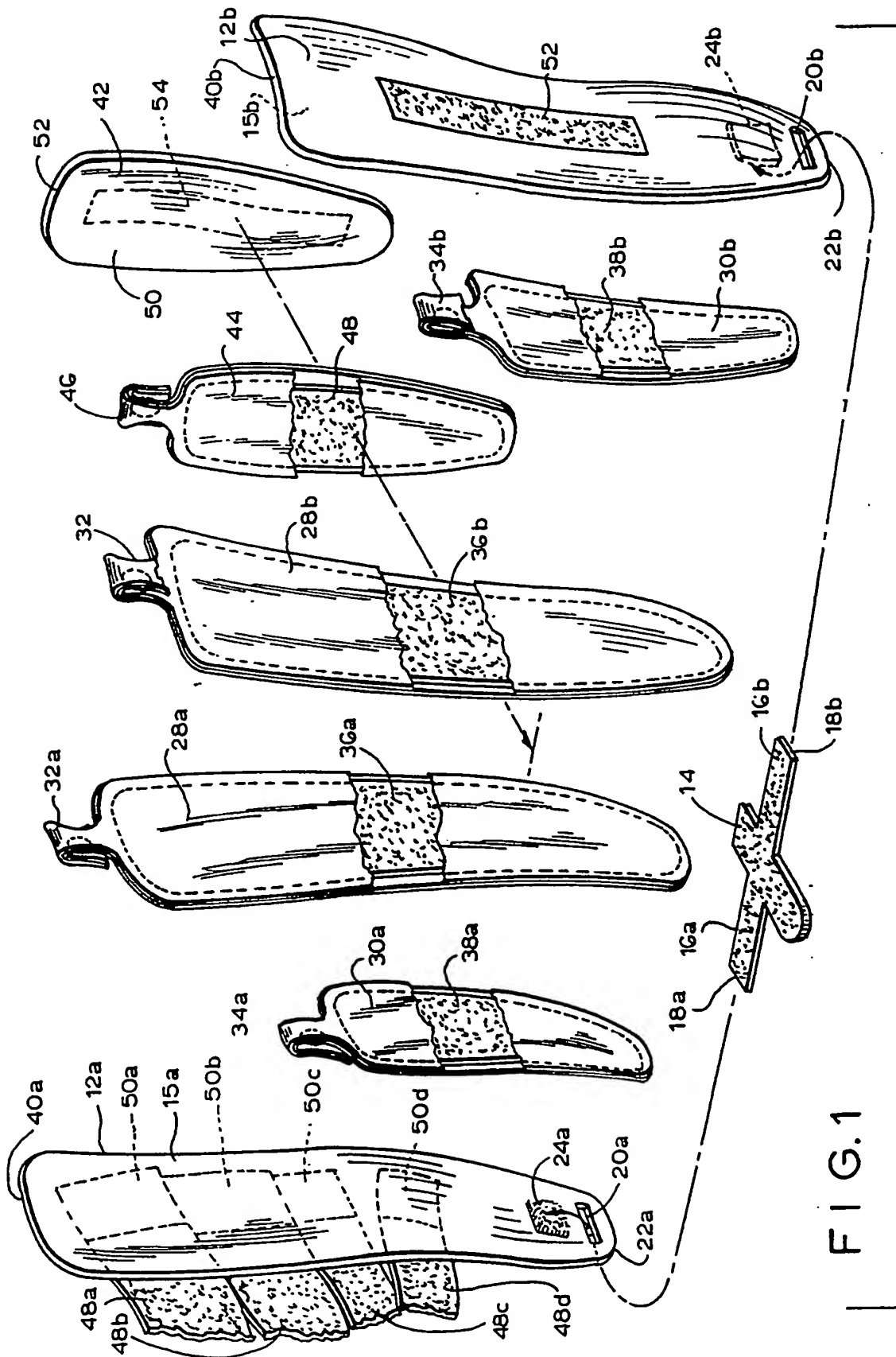
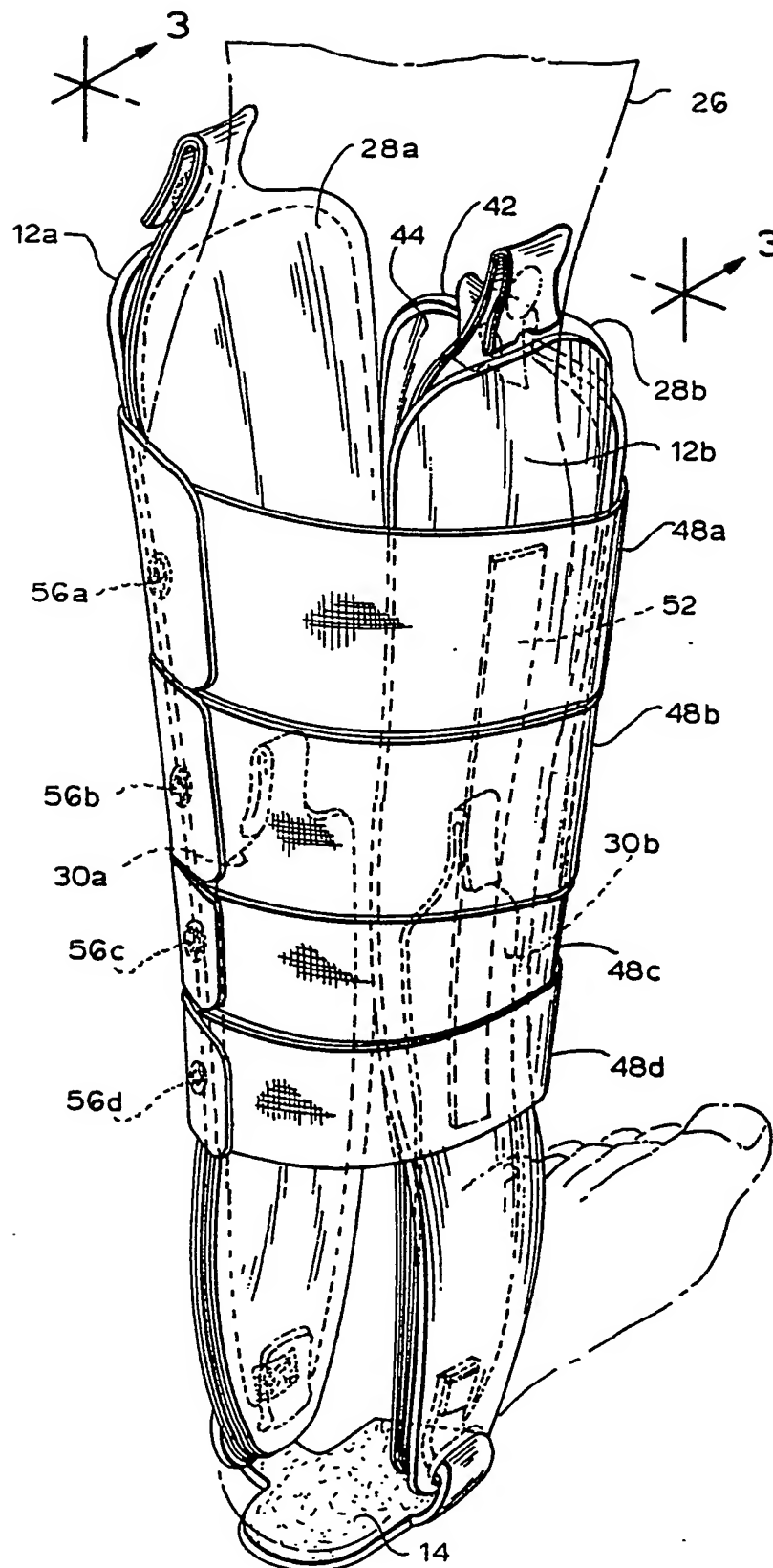


FIG. 1

FIG. 2



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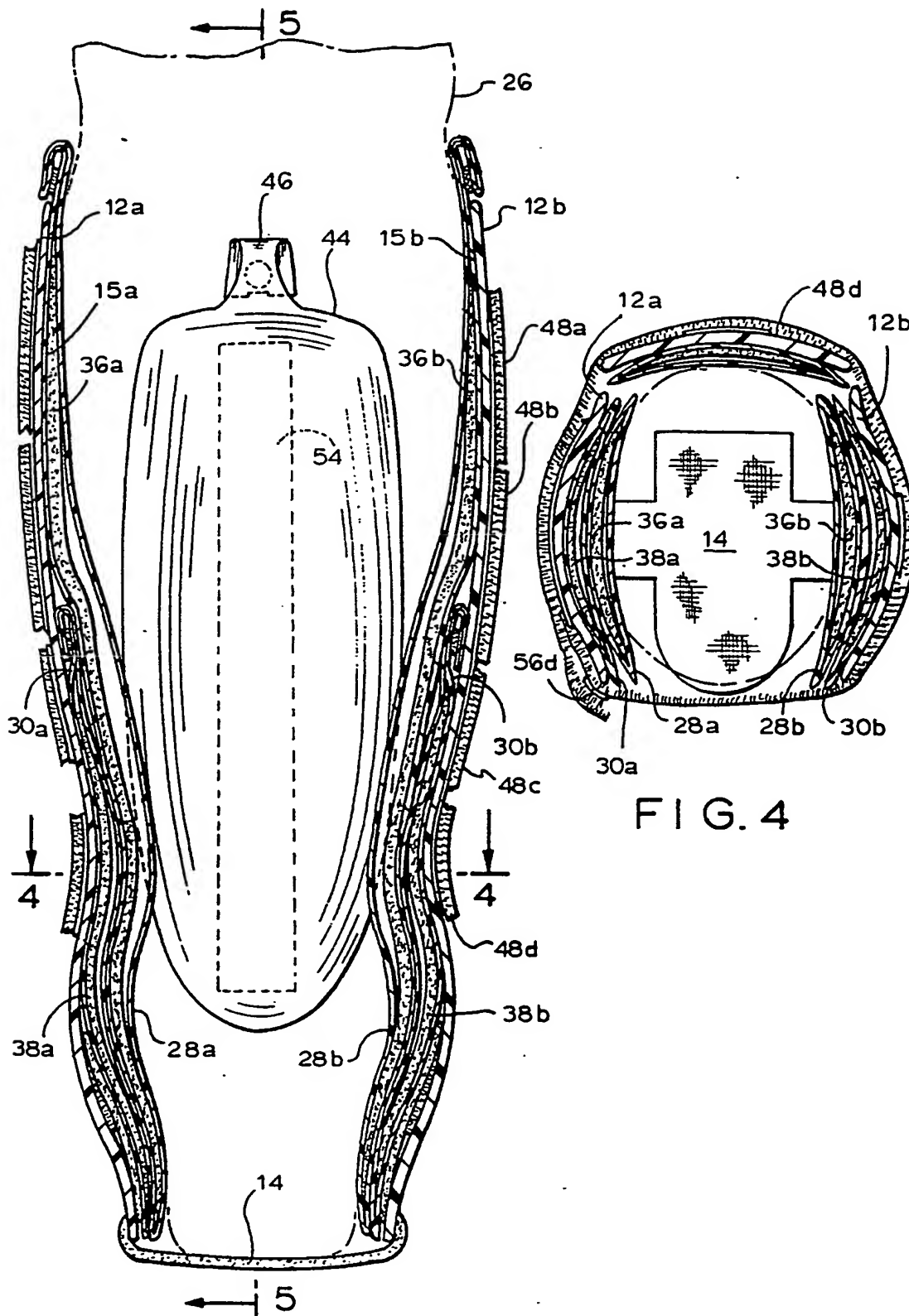


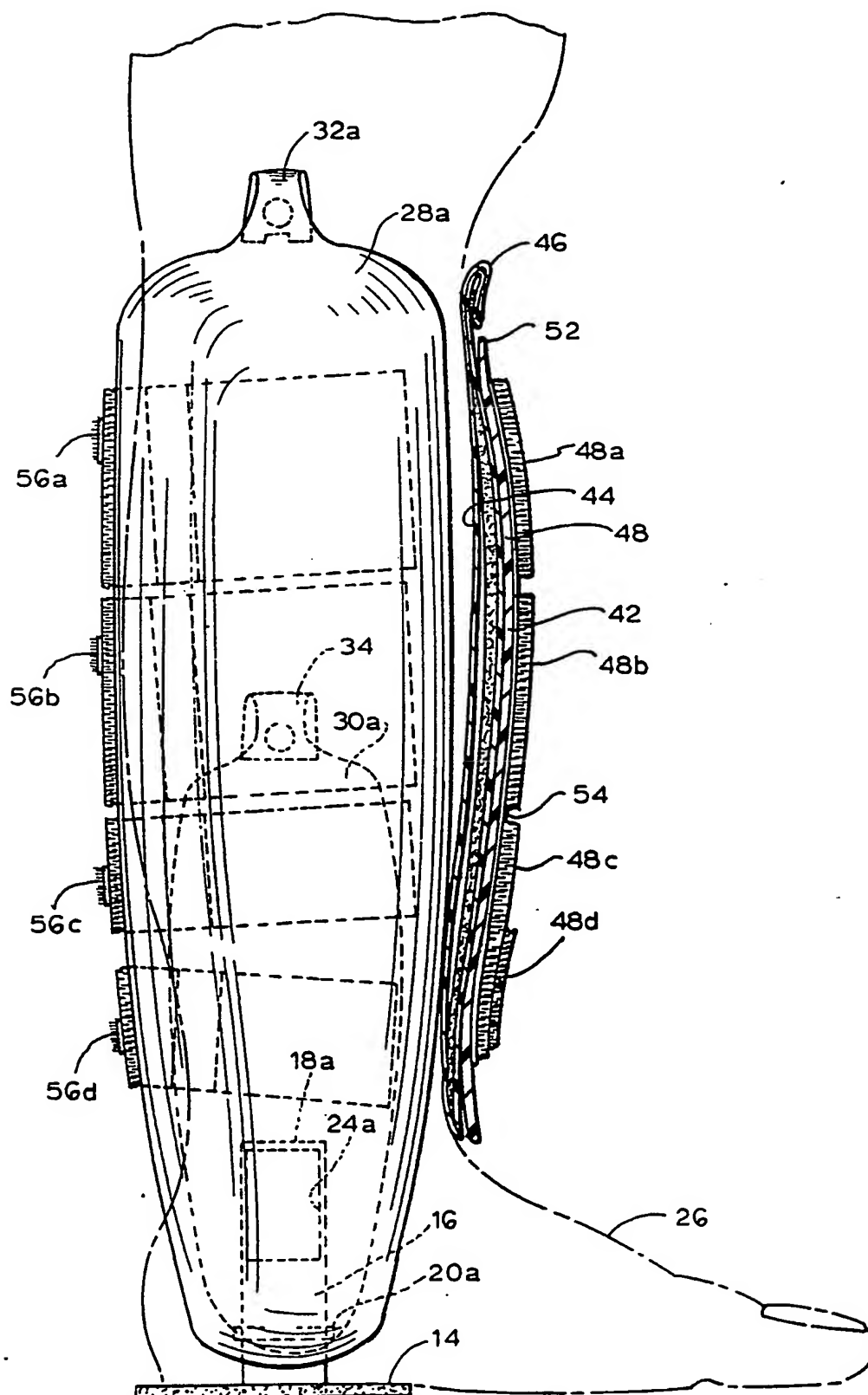
FIG. 4

FIG. 3

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FIG. 5



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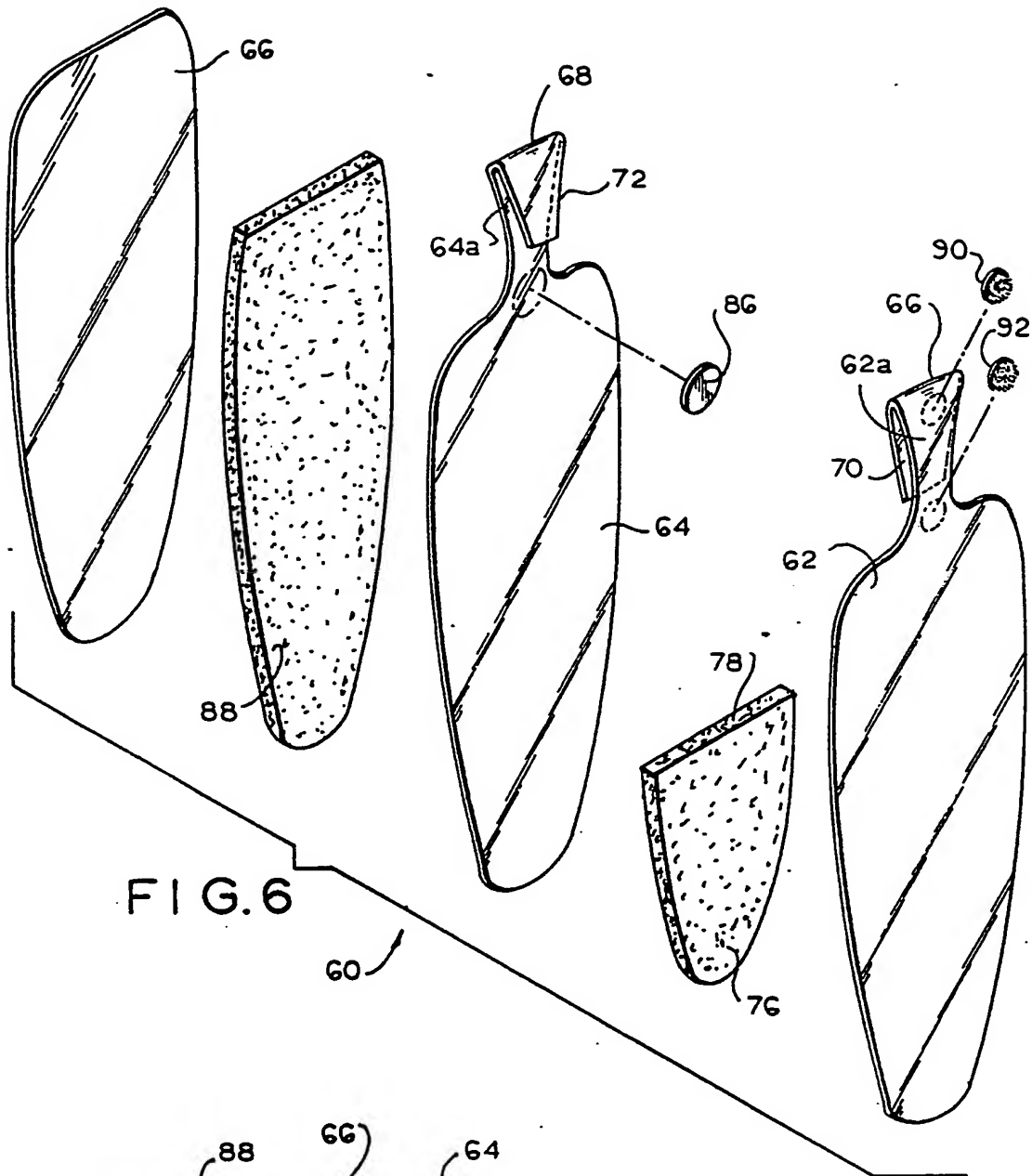


FIG. 6

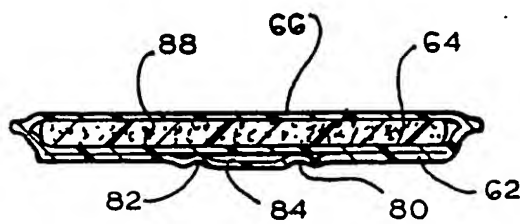
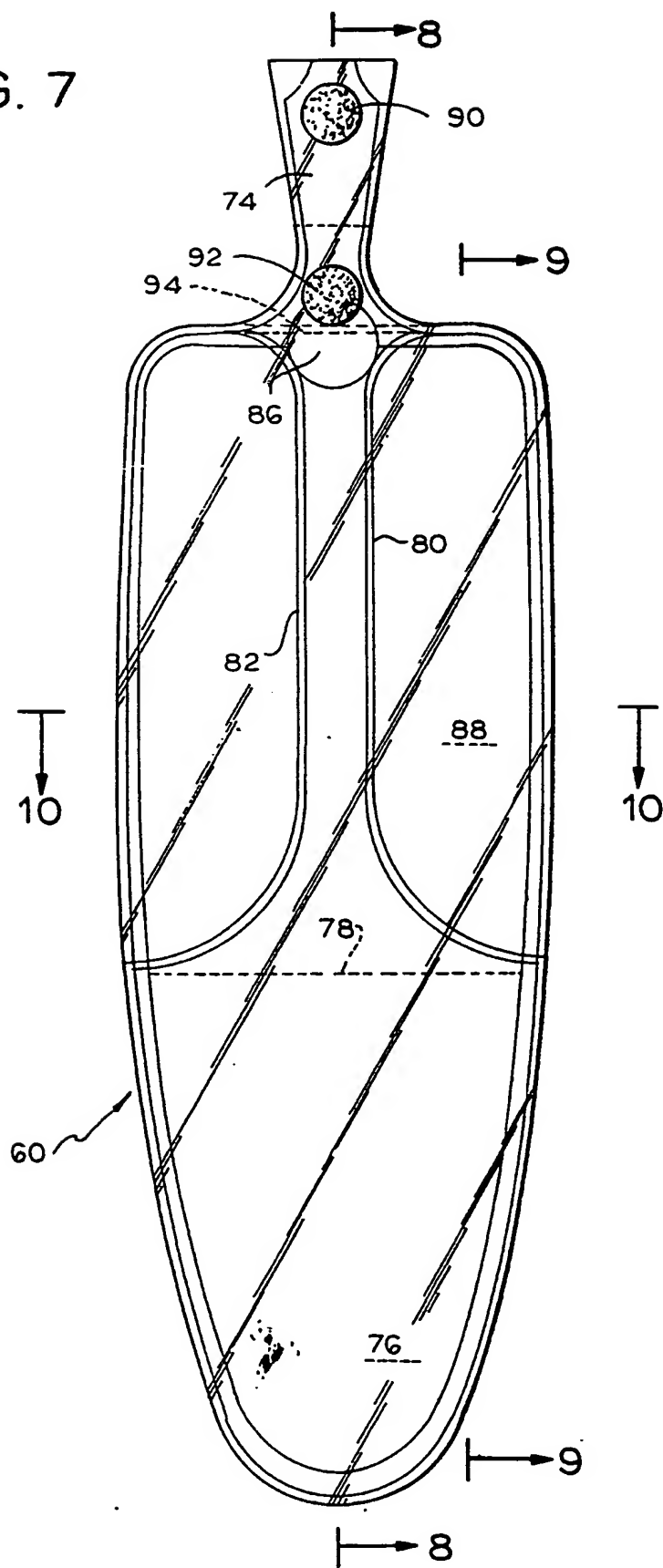


FIG. 10

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FIG. 7



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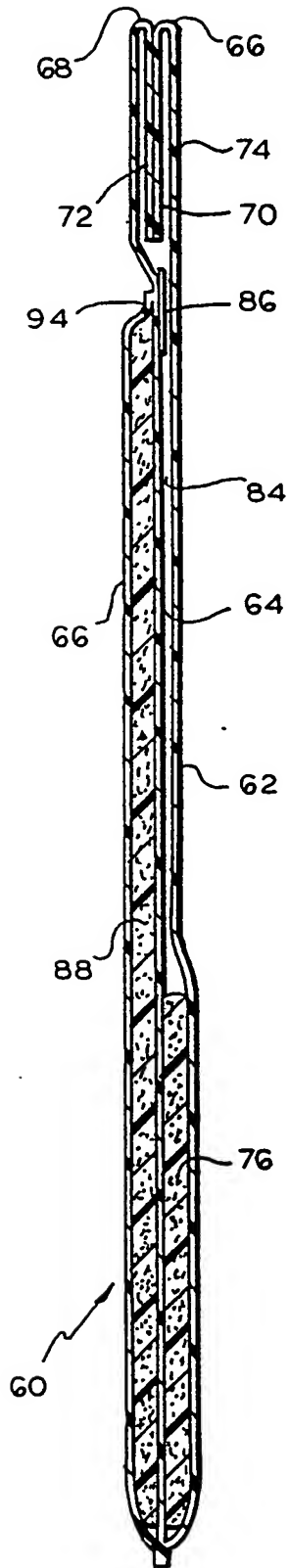


FIG. 8

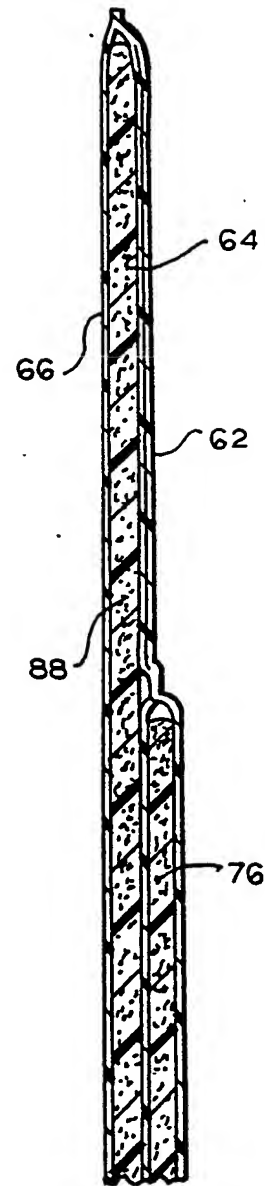
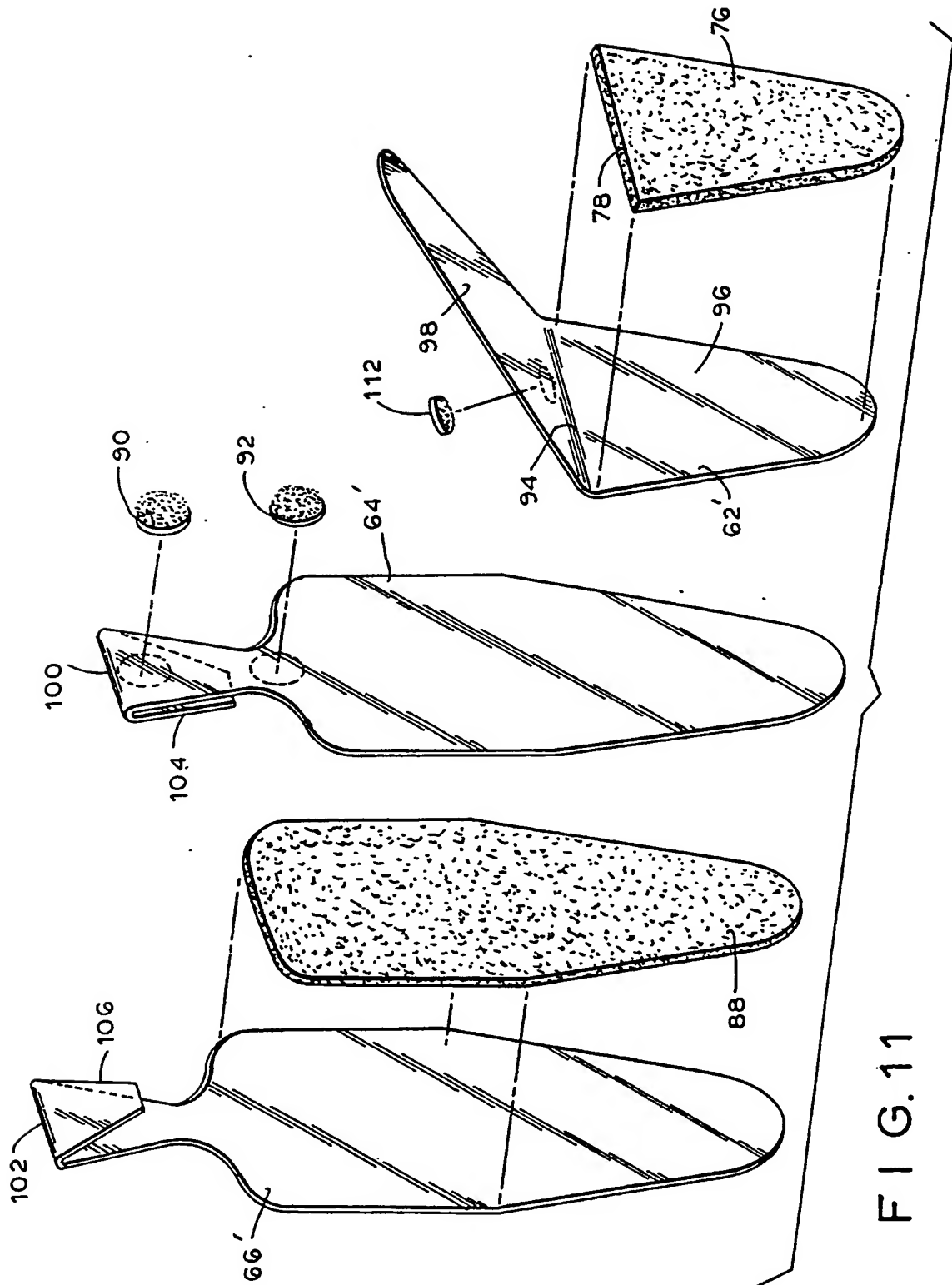
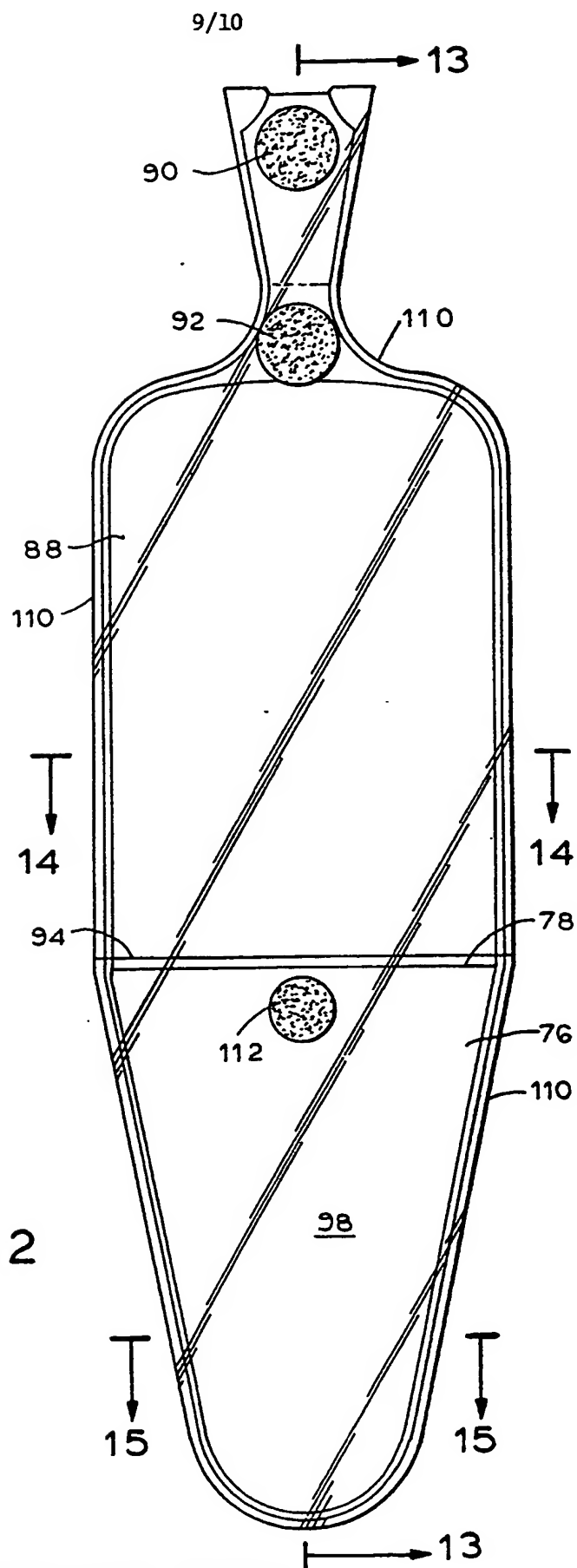


FIG. 9

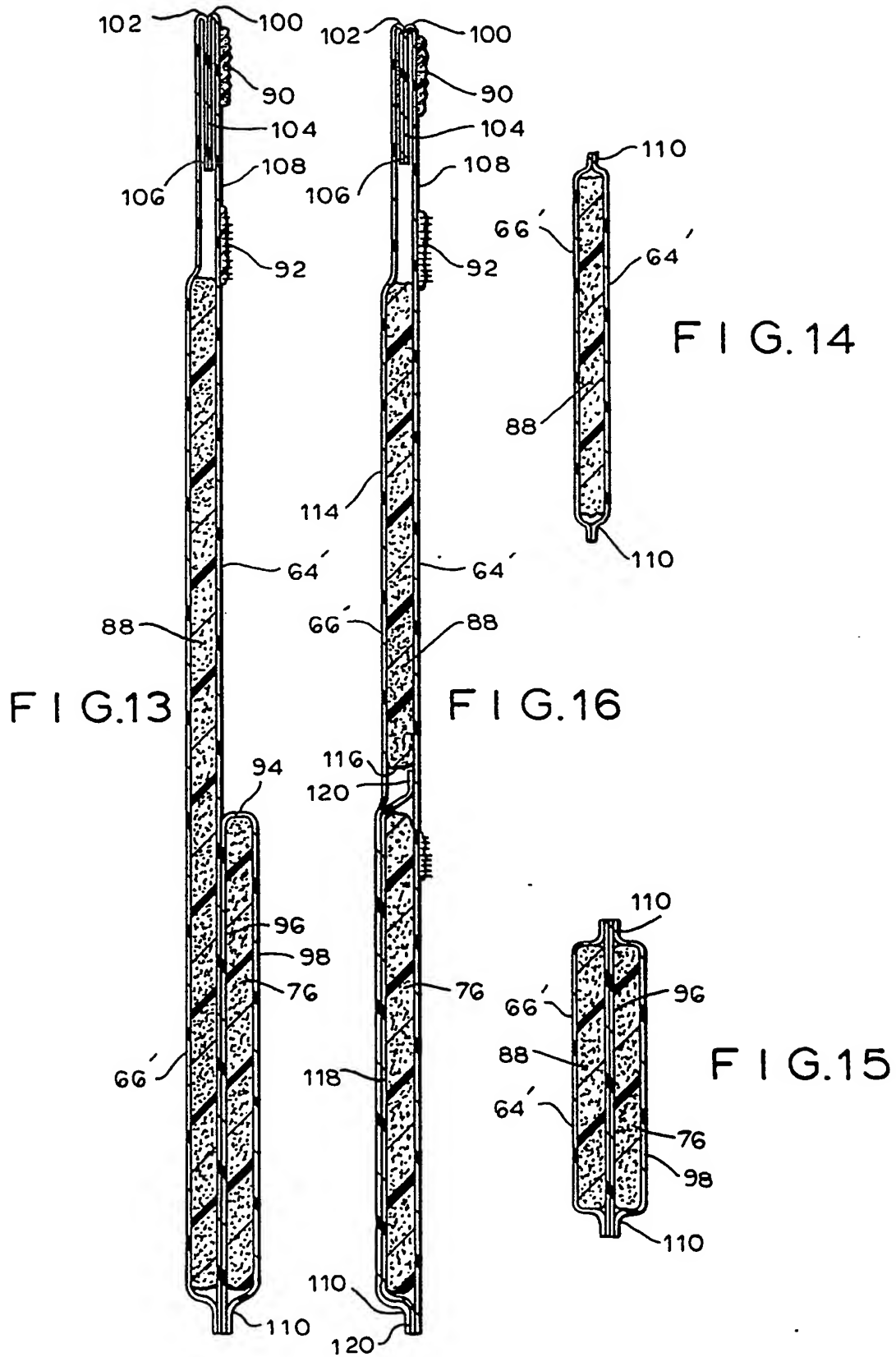


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INTERNATIONAL SEARCH REPORT

International Application No PCT/US86/02670

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ¹ According to International Patent Classification (IPC) or to both National Classification and IPC IPC (4) A61F 3/00 U.S. Cl.: 128/80H						
II. FIELDS SEARCHED <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black; margin: 5px 0;">Minimum Documentation Searched ²</div> <table style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 20%; border-bottom: 1px solid black;">Classification System</th> <th style="border-bottom: 1px solid black;">Classification Symbols</th> </tr> <tr> <td style="border-right: 1px solid black; padding: 5px;">U.S.</td> <td style="padding: 5px;">128/80H, 80R, 89R, 118, DIG. 20 2/22, 23, 413, DIG. 3</td> </tr> </table> <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black; margin: 5px 0;">Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched ³</div>			Classification System	Classification Symbols	U.S.	128/80H, 80R, 89R, 118, DIG. 20 2/22, 23, 413, DIG. 3
Classification System	Classification Symbols					
U.S.	128/80H, 80R, 89R, 118, DIG. 20 2/22, 23, 413, DIG. 3					
III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴						
Category ⁵	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸				
X	US, A, 2,694,395 (BROWN) 16 NOVEMBER 1954 See col. 6, lines 12-56 and Fig. 10	1, 2, 3, 4, 5				
Y	US, A, 1,602,454 (RIDDELL) 12 OCTOBER 1926 See the entire document	6				
Y	US, A, 3,873,997 (GOODING) 01 APRIL 1975 See Figs. 4-6	7				
E	US, A, 4,628,945 (JOHNSON, JR.) 16 DECEMBER 1986 See the entire document					
A	US, A, 4,280,489 (JOHNSON, JR.) 28 JULY 1981 See the entire document					
A	US, A, 3,955,565 (JOHNSON, JR.) 11 MAY 1976 See the entire document					
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>¹⁵ Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>						
IV. CERTIFICATION						
Date of the Actual Completion of the International Search ¹ 02 FEBRUARY 1987		Date of Mailing of this International Search Report ¹ 13 FEB 1987				
International Searching Authority ¹ ISA/US		Signature of Authorized Officer ¹⁹ C.D. Crowder				